

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

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| SHERRY COX, et al. | : | Civil Action No. C-1-01-643 |
| | : | |
| Plaintiffs, | : | Judge Beckwith |
| | : | Magistrate Hogan |
| vs. | : | |
| | : | |
| METABOLIFE INTERNATIONAL, INC. | : | |
| | : | |
| Defendant | : | |

**PLAINTIFFS' RESPONSE TO DEFENDANT'S
MOTION TO EXCLUDE PLAINTIFFS' EXPERTS**

On April 15, 2003, Defendant filed a Motion for Summary Judgment. In its motion, Defendant argued as follows:

- A. The plaintiff lacks evidence of specific causation.
- B. The plaintiff lacks evidence of general causation.
 - 1. Plaintiff's evidence does not satisfy FRE 702.
 - 2. Plaintiff's evidence does not satisfy *Daubert*.
 - 3. Plaintiff's anticipated evidence should be dismissed as "Junk Science", insufficient to create a triable issue of fact.
 - 4. The Court should take judicial notice that there is no valid scientific evidence to support the proposition that ephedra alkaloids are associated with any adverse reaction.

(See, Docket at 90, April 15, 2003, p. ii – iii.)

Plaintiff responded to Defendant's Motion for Summary Judgment, supporting the response with affidavits and reports by Plaintiffs' experts. On October 3, 2003, this Court denied Defendant's Motion for Summary Judgment. (See Docket at 117.)

On October 9, 2003, the Court entered a Notice of Final Pretrial and Trial Dates, which contained deadlines and instructions for trial. Included in the October 9, 2003 Notice is the following instruction:

Any motions in limine addressed to the admissibility of expert testimony under *Daubert* if not included in a previously filed summary judgment motion, shall be filed at least forty two (42) days final to the final pre-trial conference.

Court's Notice (Doc.at 119) (emphasis added.)

Despite the fact that Defendant had already filed a motion for summary judgment based upon *Daubert*, which the Court had already considered and denied in its Order of October 3, 2003, Defendant proceeded nonetheless to file a motion in limine, based upon *Daubert*, to exclude Plaintiffs' expert witness testimony. This motion raises the exact issues previously raised and rejected in Defendant's Motion for Summary Judgment. (See headings above.) Defendant even acknowledges that it made the same argument in its Motion for Summary Judgment, stating in its *Daubert* Motion, "as previously set forth in detail in Metabolife's Motion for Summary Judgment" (Defendant's Motion to Exclude Experts, Doc. 127, at 10.) As such, the Motion directly violates the requirements of the October 9, 2003 Notice which prohibits parties from filing *Daubert* motions which merely restate arguments previously addressed in summary judgment motions.

Moreover, Defendant makes no citations to the record when describing any of the opinions of Plaintiffs' experts to which Defendant objects. (Defendant's Motion, pp.10-11.) Instead, Defendant asserts only generalizations regarding its claim that the opinions of Plaintiff's experts are unfounded. Defendant asserts, for example, that Dr. Maggio failed to rely on sufficient evidence to form his expert opinion. (Id., p.11.) Dr.

Maggio's opinion, however, is supported by a specific and thorough review of many studies. Furthermore, Dr. Maggio analyzes the data and the significance of each study. Dr. Maggio's review of studies and articles is in addition to his detailed presentation of the pharmacologic properties and effects of ephedra. (See Maggio Affidavit Ex. 6 to Plaintiff's Response to Motion for Summary Judgment., Docket at 109.)¹

In a like manner, Defendant insinuates that Dr. Buncher is equivocal regarding the association of Metabolife and stroke. (Defendant's Motion, p.11.) However, a review of Dr. Buncher's affidavit indicates quite the opposite. Dr. Buncher attests, "these findings are evidence that this preparation [Metabolife] is powerful and causes cerebrovascular and cardiovascular problems in new users as well as those who have continued to take this material." (See Buncher Affidavit, Ex. 8, at p.3, Plaintiffs' Response to Motion for Summary Judgment, Docket at 109.)

Defendant also attacks Dr. Garraughty, who provided a detailed report and deposition outlining the severe manufacturing deficiencies at the Metabolife production plants. (See Docket, Deposition of Dr. Garraughty filed December 31, 2003.) Defendant claims that because Dr. Garraughty cannot trace any specific production deficiency directly to a pill swallowed by Ms. Beckman, (which of course no longer exist), his testimony regarding the wide variability in product contents, the lack of sanitation and cleanliness in the production facilities, and the slipshod record keeping in the production of Metabolife, must be excluded. Defendant, however, reads the rules of admissibility too strictly. Plaintiff is permitted to introduce evidence that meets the relevancy requirements of Rule 401, that is that the evidence is admissible if it has "any

¹ Plaintiff incorporates by reference Plaintiff's Memorandum in Response to Defendant's Motion for Summary Judgment, (Docket at 109), and Supplemental Response (Docket at 112.)

tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Because Plaintiff can prove that Defendant had no control over its production of Metabolife and no control over the ephedra contents in any given tablet, Plaintiff is entitled to introduce this evidence to counter Defendant’s position that each pill contained only 12 mg. of ephedrine alkaloids. Particularly where Defendant depends so strictly upon its argument that dosages of ephedra contained in each pill are too low to cause harm, Plaintiff must be permitted to introduce evidence that Defendant in fact has no proof of the total ephedrine alkaloid contents in any given tablet of Metabolife 356 because it had no control over its production facilities.

Defendant also claims that the opinion of Dr. Woo is inadmissible, despite the specific ruling by this Court rejecting the identical argument when advanced by Defendant in support of Defendant’s Motion for Summary Judgment. (Order, October 3, 2003 at 18 – 20.) Moreover, Defendant misstates the law and misstates Dr. Woo’s opinion by claiming that Dr. Woo disregards the fact that Ms. Beckman smoked one half a pack of cigarettes a day. (See Woo Aff., Ex. 11, Docket at 109.) To the contrary, Dr. Woo acknowledged the potential contributory role of cigarettes to her stroke, and opined in his affidavit concerning Mrs. Beckman that Metabolife “was a substantial contributing factor to her death.” (*Id.*, Woo Aff. at ¶ 11, 12, 15 & 16.) Ohio law does not require Plaintiffs to establish that a product is the sole cause of an outcome. *State Farm Fire & Casualty Co. v. Chrysler Corp.*, 37 Ohio St. 3d 1 (1987).²

² Defendant overlooks and never refers to the expert opinion of Dr. Heymsfield, submitted in support of Plaintiffs’ claims herein; thus presumably Defendant does not move to exclude Dr. Heymsfield.

Defendant also repeatedly refers to positions taken by the FDA, HHS and the GAO. (See Defendant's Motion to Exclude at pp.3, 4, 9, 14-16, 18-19.) However, the FDA's announcement of December 30, 2003 that it intends to completely ban the sale of ephedra containing products, completely undermines Defendant's argument. Indeed, the FDA determined that "dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury." (Ex. A.) The FDA stated:

FDA's concerns about dietary supplements containing ephedra arise in part from ephedra's mechanism of action in the body. Ephedra is an adrenaline-like stimulant that can have potentially dangerous effects on the heart. FDA's evaluation also reflects the available studies of the health effects of ephedra. This includes many studies reviewed by the RAND Corporation, which found little evidence for effectiveness other than for short-term weight loss, as well as evidence suggesting safety risks. Other recent studies have also confirmed that ephedra use raises blood pressure and otherwise stresses the circulatory system, effects that have been conclusively linked to significant and substantial adverse health effects like heart problems and strokes."

Id. at 2.

Defendant's Motion also disregards this Court's holding in its Order of December 19, 2003. In its Order denying Plaintiff's Motion to Exclude Defendant's Experts, this Court held that data existed to support the testimony of either Plaintiff's or Defendant's experts, and that the "[d]ifferences in opinions among experts do not invalidate any of the expert's opinions, but, rather, they create material issues of fact for the trier of fact to resolve." (Docket at 126, p. 4-5.)

In summary, Defendant makes the same argument in its Motion to Exclude that it previously made and lost in its Motion for Summary Judgment. Defendant also disregards this Court's Order of October 9, 2003 prohibiting repetitive *Daubert* motions, and disregards this Court's Order of December 23, 2003 holding that the evidence exists to support Plaintiff's causation claims. For these reasons, Defendant's Motion

constitutes an undue burden upon Plaintiff and the Court, entitling Plaintiff to sanctions for the time incurred in responding to this repetitive motion. Moreover, with the FDA's recent announcement that it intends to ban the sale of all products containing ephedra, Defendant's argument that Plaintiff's experts witnesses lack a reliable scientific basis for their opinions clearly lacks merit. Accordingly, Defendant's Motion to Exclude the Testimony of Plaintiff's Expert Witnesses must be denied.

Respectfully submitted,

s/ Janet G. Abaray

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CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of December, 2003, a true and correct copy of the foregoing *Plaintiffs' Response to Defendant's Motion to Exclude Plaintiffs' Experts* was electronically filed with the Clerk and was served via electronic mail service through the Clerk and/or via first class mail to the following:

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